REMARKS

Currently, claims 2-15 are pending in the application (with claims 4, 10, 11 and 15 being withdrawn from consideration as being directed to a non-elected invention).

Claims 2-3, 5-9 and 12-14 were rejected under 102(e) as being anticipated by Maclean Crawford et al. Claims 2-3, 5-9 and 12-14 were rejected under 102(e) as being anticipated by Thorne et al. Claims 2-3, 5-9 and 12-14 were rejected under 102(b) as being anticipated by Lam. Claims 2-3, 5-9 and 12-14 were rejected under 35 USC 102(b) as being anticipated by Fabozzi.

These rejections are respectfully traversed in view of the following remarks.

Applicant respectfully requests reconsideration of the claims as the added limitations set forth in the Preliminary Amendment were not addressed in the office action. In this office action, the Examiner relied on four references to reject claims 2-3, 5-9 and 12-14 as being anticipated by Maclean Crawford et al. (U.S. Patent No. 6,659,984), Thorne et al. (U.S. Patent No. 6,197,007), Lam (U.S. Patent No. 5,382,240) or Fabozzi (U.S. Patent No. 5,498,241). The only comments about each of these references

following the initial rejection sentence are applicant's unamended claim language and for three of the four references, the Examiner has listed all of the figure numbers in each of the respective references. The Examiner did not specifically identify any reference numerals in these references as relating to the claimed elements making it next to impossible to understand the Examiner's rejections.

Following an initial telephone discussion with the Examiner, applicant's representative discussed this application in detail during a telephone interview on September 16, 2004. During that telephone conference, applicant's representative requested the Examiner to identify how the cited references used in the rejections read on the presently claimed invention. The Examiner then attempted to describe how these references anticipated the claimed invention. When applicant's representative pointed out that the Examiner did not consider the limitations added by the Preliminary Amendment, the Examiner then tried to quickly read the new claim language on each of the references. In discussing each reference, applicant's representative respectfully pointed out that the newly added features were not shown in the cited references. During the discussion of the fourth reference, the Examiner told applicant's representative to just file applicant's

comments on the references and the Examiner would reconsider these rejections.

Applicant respectfully requests that the Examiner withdraw the rejections of claims 2-3, 5-9 and 12-14 because the cited references do not show or suggest the claim features in the Preliminary Amendment dated May 10, 2004. Specifically, the cited references do not disclose "a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath" as claimed in independent claim 7.

Also, these cited references do not disclose "a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion covering the needle partly" and "a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath, the protective sheath being movable relative to the tubular portion and covering the hollow needle entirely" as claimed in independent claim 13. Specifically these claims both implicitly need relative movement between the protective sheath and the hollow needle.

The present invention relates to a safety indwelling syringe

which allows safe disposal of a hollow needle after use and more particularly to a safety indwelling syringe which allows safe disposal of a hollow needle by pulling out a portion of its sheath in an easy operation.

Specifically, the fixed sheath 3 is an outer tube and it is formed with a slit 3a in the vicinity of its distal end as shown in Fig. 2. The slit 3a communicates with a front end opening 3b of the fixed sheath 3 for slidably accommodating a proximal portion of a second wing 5b coupled to a protective sheath 4. The end of the slit prevents further movement of the fixed sheath 3 relative to the protective sheath 4.

A locking means 7 is provided at a front end of the fixed sheath 3 and a proximal end of the protective sheath 4 for preventing the protective sheath 4 from separating. The locking means 7 consists of a locking slot 7a and a guide surface 7c of a tapered surface provided in the fixed sheath 3 and a locking projection 7b protruding from an outer periphery of the protective sheath 4 to be fitted into the locking slot 7a.

The protective sheath 4 is a tube with opposite opening ends and is designed to cover the hollow needle 1 when pulled out forwardly from the fixed sheath 3 and locked. Therefore, the protective sheath 4 moves relative to the hollow needle 1.

The safety indwelling syringe of this invention is supplied with the hollow needle 1 covered by the protective sheath 4 as shown in Fig. 4. In use, the hollow needle 1 is exposed as shown in Fig. 5 to be inserted into the body of a patient with the wings 5 held by an operator. After use, the second wing 5b is slid by the operator to slide the protective sheath 4 forwardly or toward the tip of the hollow needle 1, housing the hollow needle 1 in the protective sheath 4, thereby enabling safe disposal without touching the body of the hollow needle 1.

As discussed above, claim 7 recites "a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath". Also, claim 13 recites "a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion covering the needle partly" and "a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath, the protective sheath being movable relative to the tubular portion and covering the hollow needle entirely". These features are not shown or suggested by the prior art of record.

Maclean Crawford et al. relate to a blood collection set

having a needle cannula and a shield that can be driven in opposite directions to safely shield the needle cannula.

Maclean Crawford et al. disclose that in Figs. 1-3, blood collection set 10 includes a needle cannula 16, a safety shield 20 and a spring 22.

Maclean Crawford et al. also disclose that the shield 20 is an elongate tubular member having a proximal end 60 and a distal end 62. The inside diameter of the shield 20 is greater than the sum of the hub 14 plus the radial length of distal face 46 of the actuator 42. The shield 20 includes a pair of flexible wings 66 extending transversely therefrom. Additionally, the shield 20 includes an elongate slot 68 extending from the proximal end 60 toward the distal end 62 at a location that is angularly between the fins 66. The slot 68 is dimensioned to slidably receive the root 40 of the dorsal fin 38. A pair of detents 70 is formed in the slot 68 and extends toward one another at a location near the proximal end of the shield 20. An annular closure 71 is mounted over the proximal end 60 of the shield 20 and closes the proximal end of the slot 68. In Maclean Crawford et al., there is no relative movement between the needle and the protective sheath and the protective sheath does not cover the needle in one position.

Maclean Crawford et al. do not disclose that a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath as claimed in claim 7.

Maclean Crawford et al. also do not disclose a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion covering the needle partly and a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath, the protective sheath being movable relative to the tubular portion and covering the hollow needle entirely as claimed in claim 13.

It is therefore submitted that claims 2-3, 5-9 and 12-14 are allowable over Maclean Crawford et al. and the rejection based on Maclean Crawford et al. should be withdrawn.

Thorne et al. relate to safety products which generally pertain to hollow bore needle devices used in percutaneous medical procedures. Thorne et al. disclose in Fig. 5 a device 60 that is seen in a state where the needle 70 is fully retracted and shaft 192 is returned to a non-stressed state. An arm 100 has pivoted about an angle of substantially 180 degrees thereby

displacing the needle 70 approximately twice the length of the arm 100. Also, seen in Fig. 5 is one rail 198 of a pair of rails associated with the needle hub assembly 30. The rails in cooperation with the "U" shaped channel 110 restrain the needle hub assembly 30 to a slidable displacement in line with the long axis of the needle 70. Safe containment of the needle 70 within the distal segment 50 is best seen in Fig. 6. In Thorne et al., there is no relative movement between the needle and the protective sheath and the protective sheath does not cover the needle in one position.

Thorne et al. do not disclose that a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath as claimed in claim 7.

Thorne et al. also do not disclose a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion covering the needle partly and a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath, the protective sheath being movable relative to the tubular

portion and covering the hollow needle entirely as claimed in claim 13.

It is therefore submitted that claims 2-3, 5-9 and 12-14 are allowable over Thorne et al. and the rejection based on Thorne et al. should be withdrawn.

Lam relates to safety guards for useful in taking blood donations, performing blood transfusions, administering medication or the like. The guard of Lam is characterized by an outer sheath member slidably disposed about the cannula.

Lam discloses that after use of the cannula has been completed, the distal end 28 of the needle 12 is removed from the patient by pulling on the tube 14, as indicated in Figs. 4-6. Thus, the inner cannular needle 12 and its coating or tube member 18 is slidingly displaced with respect to the outer sleeve or sheath 22.

Lam also discloses that during the sliding action and as a result thereof, the engaging portions 42 ride up the ramped surface 46 of the coating or tube 18, effectively spreading the flexible engagement tabs or fingers 40 to permit the desired sliding withdrawal of the needle within the sheath 22. In Lam, there is no relative movement between the needle and the protective sheath and the protective sheath does not cover the

needle in one position.

Lam does not disclose that a protective sheath slidably movable and guided by the tubular portion of the fixed sheath between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath as claimed in claim 7.

Lam does not disclose a fixed sheath fixing the hollow needle and having a tubular portion, the tubular portion covering the needle partly and a protective sheath slidably fitted to and guided by the tubular portion of the fixed sheath, the protective sheath being movable relative to the tubular portion and covering the hollow needle entirely as claimed in claim 13.

It is therefore submitted that claims 2-3, 5-9 and 12-14 are allowable over Lam and the rejection based on Lam should be withdrawn.

Fabozzi relates to an intravenous infusion set and in particular, to a winged needle assembly usable for venipuncture that includes an integral protective member to reduce accidental needle stick from such infusion sets. Fabozzi discloses that the infusion set 10 includes a winged needle assembly 12, a section of hollow medical tubing 14, a standard fluid connector 16 and a

removable sheath 18 covering the needle as shown in Fig. 2.

Fabozzi also discloses that the wing 62 integral with the hollow tubular member 42 is pressed against the skin and the wing 36 integral with the hub is rotated into alignment with the longitudinal slot 52 as shown in Fig. 5. The tapered lead-in portion 58 at the front end of the slot 52 facilitates alignment and entry of the wing 36 or stem portion of the wing 36 into the slot. The medical tubing 14 connected to the winged needle assembly 12 is pulled back, which pulls the wing 36 or stem portion 38 through the slot 52 and withdraws the needle 22 from the vein and into the hollow tubular protective member 42.

Fabozzi also discloses that when the wing or step portion 38 reaches the lateral notch 60 at the lock-out position of the slot, the wing or stem automatically disengages from the slot. The resiliency of the plastic material of the partially split tubular member 42 causes of the slot 52 to substantially close on itself as seen at the lock-out position 56 in Fig. 6.

Also, in Fabozzi there is no relative movement between the needle and the protective sheath and the protective sheath does not cover the needle in one position.

Fabozzi does not disclose that a protective sheath slidably movable and guided by the tubular portion of the fixed sheath

between a first position where the protective sheath is housed inside of the fixed sheath and a second position where a tip of the hollow needle is entirely covered by the protective sheath as claimed in claim 7.

Fabozzi does not disclose that the fixed sheath and the protective sheath comprising locking means having a slot and a latch projection for engaging with the slot so that the locking means prevents the protective sheath from separating from the fixed sheath; and a pair of wings, at least one of the wings being coupled to the protective sheath for pulling out the protective sheath as claimed in claim 13.

It is therefore submitted that claims 2-3, 5-9 and 12-14 are allowable over Fabozzi and the rejection based on Fabozzi should be withdrawn.

For these reasons, it is believed that Maclean Crawford et al., Thorne et al., Lam and Fabozzi do not show or suggest the present claimed features of the present invention. It is therefore submitted that claims 2-3, 5-9 and 12-14 are allowable over Maclean Crawford et al., Thorne et al., Lam and Fabozzi.

If the Examiner finds a new reference to reject the present claims or uses a new interpretation with any of the current

references, it is respectfully requested that the Examiner make any such office action a non-final office action.

In view of foregoing remarks, it is respectfully submitted that the application is now in condition for allowance and an action to this effect is respectfully requested.

If there are any questions or concerns regarding these remarks, the Examiner is requested to telephone the undersigned at the telephone number listed below.

Respectfully submitted,

Date: January 3, 2005

Randolph A. Smith
Reg. No. 32,548

SMITH PATENT OFFICE
1901 Pennsylvania Ave., N.W.,
Suite 200
Washington, DC 20006-3433
Telephone: 202/530-5900
Facsimile: 202/530-5902
Nakashima010305